

INFUSION SYSTEMS, LLC

May 8, 2008

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

FAX (301) 443-1726

Request for Information from CDRH:

2008-3514
RECEIVED

FDA DFOI (HFI-35)

Infusion Systems, LLC requests a copy of the Summary of Safety and Effectiveness for the following products:

1. Codman 3000 Infusion Pump - P890055
2. Infusaid Infusion Pump - P800036
3. Medtronic Synchromed Pump - P860004

No CSEs were posted on the PMA data base for these devices. ISLLC would appreciate receiving these documents via e-mail, If possible, Kindly send them to the attention of Peter Lord:

PLord@advancedbionics.com

Sincerely yours,



Gerda Resch, MT (ASCP) RAC

Consultant, Regulatory Affairs

Infusion Systems, LLC

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